REMARKS

This is a full and timely response to the final Office Action mailed February 6, 2008. Reconsideration of the application and allowance of presently pending claims as amended, are respectfully requested.

A. Present Status of Patent Application

Independent claims 1, 23 and 63 have been directly amended, and the remaining claims indirectly amended as they depend from one of the amended Independent claims. Claims 34-37 are cancelled hereby, and new claims 98 and 99 added. Support for the amendments to claims 1 and 23 is found at least at paragraph 0006 of applicants' specification. Support for new claims 98 and 99 is found at least at paragraph 0029 of applicants' specification.

Claims 1-15, 18-20, 23-25, 28-31, 38-40, 63-78 and 98-99 remain pending.

B. Response to Rejections

1. Provisional Double Patenting Rejection

The provisional rejection of claims 1-16, 18-20, 23-36, 38-40, 63-72, and 74-76 on the ground of nonstatutory obviousness-type double patenting over the claims of co-pending U.S. application 11/187,757 has again been noted. Should the provisional rejection mature into a double-patenting rejection which is the sole ground of rejecting the present claims, consideration will be given to filing the appropriate terminal disclaimer.

2. Rejection under 35 U.S.C. §112

Claims 1-20, 23-25, 28-31, 34-40 and 63-78 were rejected under 35 U.S.C. §112 first paragraph, as allegedly non-enabling. It was admitted that the specification is enabling for methods of treating a pulmonary fungal infection. It was contended, however, that the specification is not enabling for **preventing** a pulmonary fungal infection. This rejection is respectfully traversed as to the pending claims.

As an initial matter, applicant does not contend that the invention as claimed is for a method of preventing (in an absolute sense) a pulmonary fungal infection; rather **prophylaxis** against a pulmonary fungal infection is described and claimed. The term "prophylaxis" is well supported in the specification, and is readily understood by one skilled in the art to mean the mitigation, amelioration, slowing, impeding or otherwise inhibiting the onset, symptoms, spread or results of a particular condition, but not the outright elimination thereof. Indeed in the field of medical diagnosis and treatment of diseases, it is well understood that there are no absolutes.

For the foregoing reasons, applicant contends that the specification is fully enabling even as to the unamended claims (see paragraphs 0006-0014, 0028 and 0038-0040, for example). Nonetheless, to improve clarity, applicant has amended claims 1, 23 and 63.

Additionally, the applicants respond as follows to certain of the *In re Wands* factors described in MPEP 2164.01(a) and cited by the Examiner to determine whether a disclosure meets the enablement requirement:

Factor (1) - The nature of the invention The Examiner has noted the claims are drawn to a method, however applicants have amended the preamble to claim 1 (as well as claims 23 and 63) to recite a method of **providing therapy against** pulmonary fungal infections. This limitation, which expressly includes both treatment therapy and prophylactic therapy is expressly disclosed *in ipsis verbis* in paragraph 0006 of applicants' specification.

Factor (2) - The breadth of the claims The Examiner contends that the claims read on completely **preventing** pulmonary fungal infection. Even as to the unamended claims, applicants disagree. Nowhere in the specification or in any of the claims does the term "prevent" appear, nor are there any express or implied claims to prevention as construed by the Examiner. The position taken in interpreting "prophylaxis" as "prevention" is equivalent to equating "treating" to "curing", a plainly untenable position. Moreover, a search using the USPTO database revealed 1555 occurrences of "prophylaxis" and "method" in the claims, thus the term prophylaxis is well-accepted, and known to the art. Applicants submit that as amended the breadth of the claims is commensurate with the disclosure in the specification. It is noted that mere breadth of claim scope does not imply a lack of enablement; rather enablement is related to how well

the claim is defined. Applicants submit that the claims are well defined, and fully enabled by the specification.

Factor (3) The state of the prior art The Examiner alleges that there is little or no prior art relating to pulmonary fungal infection. However, the Examiner misstates the standard by limiting to art relating to **preventing** pulmonary fungal infections. As addressed above, prevention is not the criterion. As to art relating to treating pulmonary fungal infections, there is sufficient to lead one skilled in the art to understand applicants claimed invention. In this regard, even the *Ponikau* reference cited by the Examiner describes **preventing** non-invasive fungus induced mucositis (see the Abstract).

Factor 4. - The level of predictability in the art A therapeutically-active drug may turn out to be an unsuitable drug candidate if it exhibits toxicity or side effects, but this would not imply that predictability of therapeutic art is low. Therefore, Applicants submit that the predictability of therapeutic art is high.

Factors 6 and 7 – The amount of guidance presented/the quantity of experimentation needed The specification provides full and complete guidance as to how the claimed formulation can be used to treat pulmonary fungal infections. See for example, paragraphs 0035-0041. Furthermore, it is to be noted that compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. An example may be "working" or "prophetic." An applicant need not have actually reduced the invention to practice prior to filing. In *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987), as of Gould's filing date, no person had built a light amplifier or measured a population inversion in a gas discharge. The Court held that "The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it." 822 F.2d at 1078, 3 USPQ2d at 1304 (quoting *In re Chilowsky*, 229 F.2d 457, 461, 108 USPQ 321, 325 (CCPA 1956)). See also MPEP §2164.02.

The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).

A skilled artisan will be able to use the formulations of the invention according to the guidance provided in the specification, for the treatment of pulmonary fungal infections. Therefore, applicants submit that specification is enabling with respect to 35 USC § 112, paragraph 1, for all pending claims. Thus one skilled in the art would readily be able to perform the steps of: (1) ascertaining the type of fungal infection existing in a patient (or the type of pulmonary fungal infection to which a given patient would be most susceptible, given the patient's condition; (2) selecting an antifungal known to be efficacious against said infection; and (3) selecting a dose and regimen to treat said infection.

3. Rejection under 35 U.S.C. §103(a) over *Ponikau.*

Claims, 1-15, 23-35, 28-31, 34 and 35 were rejected under 35 USC 103 (a) as allegedly anticipated by *Ponikau*, US 6207703.

Applicants traverse this rejection for at least the following reasons.

Ponikau is limited to teaching methods and materials for treating a non-invasive fungus induced rhinosinusits, and has nothing to do with pulmonary fungus or pulmonary delivery and in particular does not teach or suggest methods and formulations comprising powders for pulmonary delivery. As such *Ponikau et al.* does not teach or suggest the elements of applicants' amended claims, in particular the features of **porous, aerodynamically light** powders, having the claimed bulk density and mass median aerodynamic diameter characteristics for delivery to the lungs to treat infections of the lungs.

Additionally, as to the rejection of the dependent claims 2-15, 18-20, 24-25 and 28-31, as the independent claims are allowable over the prior art of record, then their dependent claims are allowable as a matter of law, because these dependent claims contain all features/elements/steps of their respective independent claim. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Additionally and notwithstanding the foregoing reasons for the allowability of independent claims 1, and 23, the dependent claims recite further features/steps and/or combinations of features/steps (as is apparent by examination of the claims themselves) that are patentably distinct from the prior art of record. Hence, there are other reasons why these dependent claims are allowable.

4. Rejection under 35 U.S.C. §103(a) over *Ponikau* in view of Straub *et al.*

Claims 16,-20 and 36-40 were rejected under 35 USC 103 (a) as allegedly anticipated by *Ponikau* in view of *Straub et al.*, US 6395300.

Applicants respectfully traverse this rejection for the following reasons. Each of the rejected claims are dependent claims, and for reasons advanced in paragraph 3 above, the Independent claims are allowable over the cited reference(s), then their dependent claims are allowable as well. See *In re Fine* (supra.)

Thus, *Ponikau et al.* does not teach or suggest the features of Independent claims 1 or 23, nor do the references individually, or the combination thereof teach the subject matter of remaining dependent claims 16-20 or 38-40.

Straub et al. is inapposite because Straub et al is drawn to a method of improving rate of dissolution of orally or parenterally-administered drugs, especially those with low aqueous solubilities. Straub thus does not teach suggest or disclose anything relating to aerodynamically-light particles for **pulmonary administration** directly to the lung, and in particular does not teach suggest or disclose a particulate formulation having the properties as claimed and wherein the formulation is administered by the claimed method to treat pulmonary fungal infections Straub et al is instead confined to disclosing a method of making a porous drug particle by a process involving dissolving a drug in a volatile solvent to form a drug solution, combining a pore forming agent with the drug solution to form an emulsion, suspension, or second solution, and removing the solvent and pore forming agent from the emulsion, suspension, or second solution to yield the porous matrix of drug. As such, there is no motivation or suggestion to combine Straub et al with Ponikau, as the two relate to entirely different routes of administration and purposes.

As such, it is respectfully requested that the §103(a) rejection of claims 16-20, and 38-40 be withdrawn.

5. Rejection under 35 U.S.C. §103(a) over *Ponikau* in view of *Unger.*

Claims 17-19 and 37-39 were rejected under 35 USC 103 (a) as allegedly anticipated by *Ponikau* in view of *Unger,* US 2001/0018072.

Applicants respectfully traverse the rejection of the remaining dependent claims (17-19 and 37-38) for the same reasons advanced in paragraphs 3-4 above. The combination of *Ponikau* with *Unger* does not change this conclusion.

Unger teaches non-specifically delivery of active agents to a patient's lungs, a concept which is old in the art. *Unger*, either alone, or combined with *Ponikaul*, does not teach, suggest or disclose applicants specifically claimed method of treating and/or preventing pulmonary infections, including administering in the claimed dosage and regimen.

Applicants note that no art rejection was made in respect of pending Claims 63-78. As the rejections thereof under §112, and double patenting, have been addressed above, accordingly applicant respectfully contends these claims are in condition for allowance, and such action is respectfully requested.

Conclusion

In view of the foregoing, applicants submit that pending claims 1-15, 18-20, 23-25, 28-31, 38-40, 63-78 and 98-99, satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal of all rejections is respectfully requested and a prompt mailing of a Notice of Allowance is solicited.

Please grant any extensions of time required to enter this response and charge any additional required fees to deposit account 50-0348. If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 283-6790.

Respectfully submitted,
Nektar Therapeutics

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